

## REMARKS

### I. Introduction

In response to the Office Action dated February 11, 2003, claims 1-3 have been amended, and new claims 5-12 have been added. Claims 1-12 remain in the application. Reconsideration of the application, as amended, is requested.

### II. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter. The claims are supported by the application as originally filed, as indicated below.

The amendment to claim 1 merely introduces the limitations of claim 2 as originally filed, and accordingly is of identical scope to original claim 2.

The amendment to claim 2 is supported by the specification at page 3, lines 15-17.

The amendment to claim 3 merely clarifies that "lentivirus" refers to the lentivirus of the host infection recited in the initial phrase of claim 1.

New claims 5 and 6 are supported by original claims 3 and 4, and clarify that lentivirus vector can be derived from HIV or HIV-1, as described in the specification (e.g., at page 8, lines 15-18).

New claim 7 is supported by the specification in Example 2, at pages 17-19.

New claim 8 is supported by the specification at page 16, lines 13-16.

New claim 9 is supported by the specification at page 3, lines 15-19.

New claim 10 is supported by the specification at page 3, lines 20-22.

New claims 11 and 12 are supported by the specification at page 3, lines 23-27.

### III. Sequence Rules

At page 2 of the Office Action, Applicants were notified that the application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the specification contains sequences that are not identified by their sequence identifier. Applicants have amended the specification at

page 16, lines 21-23, to introduce the sequence identifiers for SEQ ID NO: 1 and 2. Applicants' representative has reviewed the specification and figures and determined that no additional sequences are disclosed therein. Accordingly, the initial CRF and paper copies of the Sequence Listing are correct and a substitute Sequence Listing is not required.

#### **IV. Non-Art Rejections**

At page 3 of the Office Action, claims 3 and 4 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection was based on an ambiguous antecedent basis for the recitation of "said lentivirus".

Applicants have amended claim 3 to clarify the recitation of "said lentivirus". Because claim 4 depends from claim 3, this amendment to claim 3 clarifies claim 4 as well.

#### **V. Prior Art Rejections**

At pages 3-5 of the Office Action, claims 1-3 were rejected under 35 U.S.C. §102(a) as being anticipated by Wong-Staal et al., U.S. Patent No. 5,650,309 (Wong-Staal); and under 35 U.S.C. §102(e) as being anticipated by Wong-Staal; claims 1-4 were rejected under 35 U.S.C. §102(a) as being anticipated by Sodroski et al., U.S. Patent No. 5,665,577 (Sodroski); and under 35 U.S.C. §102(e) as being anticipated by Sodroski. At pages 5-6 of the Office Action, claims 1-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Irwin et al., and under 35 U.S.C. §103(a) as being unpatentable over Naldini et al. and Irwin. Applicants respectfully traverse these rejections for the reasons discussed below.

Independent claim 1 is generally directed to a method for treating a host infected with a lentivirus comprising exposing the host to a lentivirus vector and a biologically acceptable carrier, excipient and diluent, wherein the lentivirus vector has an intact 5' lentivirus LTR. The cited references do not teach nor suggest these various elements of Applicants' independent claim.

Wong-Staal describes replication-defective vectors encoding an anti-viral agent. Wong-Staal teaches that the vector must encode an anti-viral agent, even where HIV is the target virus (see, e.g., column 15, lines 15-29). Wong-Staal neither teaches nor suggests a method of treating lentivirus infection in a host comprising exposing the host to a lentivirus vector having an intact 5' LTR.

Moreover, Wong-Staal teaches that, when the virus is derived from HIV, the LTR is modified (see, e.g., column 2, lines 48-51). Accordingly, Wong-Staal teaches away from Applicants' invention because it explicitly requires two components to the therapeutic vector: a cellular transducing portion and an anti-viral portion.

Sodroski describes a discovery relating to identification of a region involved in making packaging defective HIV vectors and teaches the use of such vectors in conjunction with a second vector containing a preselected gene. Although Sodroski mentions packaging defective vectors that contain an HIV-1 LTR as promoter, such as in claim 10 noted in the Office Action, Sodroski does not teach that such a vector can be used in a method of treating lentivirus infection. Sodroski cannot anticipate Applicants' claims because Sodroski fails to teach treating lentivirus infection in a host by exposing the host to a lentivirus vector having an intact 5' LTR. Instead, Sodroski teaches away from Applicants' invention because it describes the need for combinations of vectors (see, e.g., column 6 and columns 12-14).

Irwin describes injection of recombinant retroviral vectors carrying HIV-1 rev and env genes into muscle and a subsequent CTL response. Naldini describes a lentiviral transfer vector capable of delivering a gene to a cell. Neither of these references, alone or in combination, teaches or suggests treating lentivirus infection in a host by merely exposing the host to a lentivirus vector having an intact 5' LTR.

Thus, Applicants submit that independent claim 1 is allowable over Wong-Staal, Sodroski, Irwin, and Naldini. Further, dependent claims 2-12 are submitted to be allowable over Wong-Staal, Sodroski, Irwin, and Naldini in the same manner, because they are dependent on independent claim 1, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 2-12 recite additional novel elements not shown by Wong-Staal, Sodroski, Irwin, and/or Naldini.

**VI. Conclusion**

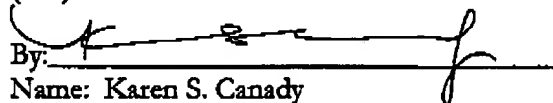
In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP  
Attorneys for Applicant(s)

Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, California 90045  
(310) 641-8797

Date: June 11, 2003

By:   
Name: Karen S. Canady  
Reg. No.: 39,927

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